

Application no.: 10/729,069

Docket no.: SLK-2016-UT

**REMARKS**

The Office required a four-way restriction of original claims 1-20 in the outstanding Office action, and required an election of species. Applicants' elections are set forth hereafter.

**Restriction Requirement**

Applicants traverse the requirement for restriction between subject matter of Group I (claims 1-14) and Group II (claims 1-15) as (1) there is no undue burden associated with searching and examining subject matter of Group II once the elected subject matter of Group I is searched, and (2) binding legal precedent forbids restriction within a claim.

There is no undue search burden because subject matter of Group I is generic with respect to subject matter of Group II, and a search pertaining to subject matter of Group I should therefore encompass the subject matter of Group II. Specifically, once the Office performs a search for the methods of detecting cell fusion in claims 1-14, the same search should cover methods for identifying a molecule that modulates cell fusion in claim 15. Thus, no undue search burden is imposed by examining subject matter of Group I and Group II.

Further, the Office has required restriction between subject matter within each of claims 1-14 as the subject matter of the claims is divided between Group I and Group II. This practice is impermissible according to controlling legal precedent. *See In re Watkinson*, 14 USPQ 2d 1407 (Fed. Cir. 1990) citing *In re Weber*, 198 USPQ 328, 332 (CCPA 1978) and *In re Haas*, 198 USPQ 334, 336 (CCPA 1978). The courts have definitively ruled the statute authorizing restriction practice (i.e., 35 U.S.C. § 121) provides no authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. In these decisions, the courts expressly ruled there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Office to fashion such a rejection. As noted in *In re Weber* at 334:

The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim, no matter how broad, which means no matter how many independently patentable inventions may fall within it.

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Alleging that a particular claim represents multiple "patentably distinct" inventions is a *de facto* rejection of the patentability of the claim because the claim cannot issue as drafted. In this regard the court noted in *In re Weber, supra*:

As a general proposition, an applicant has a right to have each claim examined on the merits. If an applicant submits a number of claims, it may well be that pursuant to a proper restriction requirement, those claims will be dispersed to a number of applications. Such action would not effect the rights of the applicant eventually to have each of the claims examined in the form he considers to best define his invention. If, however, a single claim is required to be divided up and presented in several applications, that claim will never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of fragments would not be described in the specification (emphasis added).

Instead of improperly imposing restriction of a given claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim (see 37 C.F.R. § 1.146). This practice strikes an appropriate balance between administrative concerns of the Office and the clear constitutional and statutory rights of the inventor to claim an invention as it is contemplated. See MPEP at § 803.02; *In re Wolfrum*, 179 USPQ 620 (CCPA 1973); and *In re Kuehl*, 177 USPQ 250 (CCPA 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution nor does it force an Applicant to file multiple divisional applications that are incapable of capturing the intended scope of the application. Here, it should be clear that the added cost of filing and prosecuting two patent applications does not strike an appropriate balance between the administrative concerns of the Office and the Applicants' statutory rights as inventors.

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Thus, restriction between subject matter of Groups I and II is impermissible according to controlling legal precedent, and it is respectfully requested that the Office examine the subject matter of claims 1-15.

Applicants hereby elect subject matter of Group I (claims 1-14) with traverse. Claims 16-20 are cancelled herein as they are directed to non-elected subject matter of Groups III and IV. Applicants reserve the right to pursue subject matter no longer pending after cancellation of these claims in a related patent application.

#### Species Election Requirement

The Office also required election of particular species. The Applicants hereby elect the following species with traverse: (a) 293 cell as the first cell; (b) 293 cell as the second cell; (c) for the first cell, HIV gp160 as the viral envelope protein and an  $\alpha$ -fragment of  $\beta$ -galactosidase as the reporter fragment; and (d) for the second cell, CD4 as the viral envelope protein receptor and an  $\Omega$ -fragment of  $\beta$ -galactosidase as the reporter fragment. It is not clear to the Applicants whether the Office requires a species election for an optional co-receptor, but if there is such a requirement, the Applicants elect co-receptor CCR5 in conjunction with CD4. Also, the compound TAK-779 is elected as a species for search and examination of claim 15.

The Applicants traverse the species election requirement on several grounds. First, many of the components are interchangeable and they should not be limited to the first cell or the second cell. For example, the first cell or the second cell may contain either the  $\alpha$ -fragment or the  $\Omega$ -fragment of  $\beta$ -galactosidase. Second, the first cell and second cell may be the same cell type or a different cell type. Third, search and examination of claim 15 should not require an election of a cell fusion inhibitor molecule as the claim is directed to a method of identifying such a molecule, not the molecule *per se*.

The Applicants expect that the Office will extend examination to other species generic to the claims upon a finding that the claims are novel and non-obvious after examination of the elected species.

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**CONCLUSIONS**

Applicants respectfully request examination of claims 1-15 on the merits. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at (858) 623-9470 so that they may be promptly resolved.

In the unlikely event the transmittal letter is separated from this document and the Office determines that an extension and/or other relief is required, Applicants petition for any required relief, including extensions of time, and authorize the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account 503473**.

Respectfully submitted,

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